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09/470,874	12/22/1999	MARC MEHRZAD JALISI	ACS-58267 (1700X)	6721

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FULWIDER PATTON LLP  
HOWARD HUGHES CENTER  
6060 CENTER DRIVE, TENTH FLOOR  
LOS ANGELES, CA 90045

EXAMINER
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MACNEILL, ELIZABETH

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3767

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



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**MAILED**  
**FEB 06 2008**  
**GROUP 3700**

**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 09/470,874  
Filing Date: December 22, 1999  
Appellant(s): JALISI ET AL.

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Thomas M Majcher  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 2 January 2008 appealing from the Office action mailed 14 March 2007.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

5,776,080	THOME ET AL	7-1998
WO 96/25969	FAGAN et al	8-1996

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 1-15, 17, 19-27 and 29 are rejected under 35 U.S.C. 103(a) as obvious over THOME et al (US 5,776,080) in view of FAGAN et al (WO 96/25969, cited by applicant).

Regarding claim 1, Thome teaches a medical guidewire having a heat-treated elongate member comprising a composite core (150), the composite core section including an inner core (154) formed of Hipercor (Col 13 line 50) wire, and a layer formed of a superelastic material (178, Nitinol), and a second layer concentrically arranged about the layer formed of superelastic material (176), wherein the layer is arranged about the inner core (See Fig 25) (Col 16 lines 54-end).

Thome does not teach that the inner core is formed of a precipitation hardened material. Fagan teaches a precipitation hardened material (stainless steel) for use in a medical guide wire (Abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the precipitation hardened material of Fagan with the guide wire of Thome as an alternate material.

Regarding claim 8, Examiner takes the "flexible body overlying the distal section" to be resin 176. Thome teaches the precipitation hardenable material to be Hipercor 50B, which contains cobalt and iron (and trace elements), and Fagan discloses an alloy of nickel, cobalt, molybdenum and chromium (MP35N, page 17 lines 19) (also applicable to claims 10, 13, 14, and 15).

Regarding claim 26, Thome further discloses a flexible coil (182) disposed at a distal end of a distal section of the guidewire, wherein the precipitation hardened material and superelastic material extend from the proximal section to at least through a part of a length of the flexible coil. Fig 26A.

Regarding claim 27, Thome further discloses that the distal section is tapered (Fig 27)

Regarding claims 2-4, the modulus of elasticity of the composite elongate is about  $28 \times 10^6$  to  $29 \times 10^6$  (Fagan page 17 line 23).

Regarding claims 5-7, the ultimate tensile strength of the composite elongate is 300 k.s.i. (Fagan page 17 line 26).

Regarding claim 9, the composite core is precipitation hardenable stainless steel (Fagan)

Regarding claim 17, the inner core and outer layer are independently formed (Thome)

Regarding claim 19, the first layer is Nitinol (Thome)

Regarding claims 20, 21, and 29 a second layer (158) is disposed at least in part concentrically about the first layer, second layer of substantially the same material as the first layer (Thome)

Regarding claims 23 and 25 see distal taper at Fig 25 showing exposed inner core extending beyond layer 176.

Regarding claims 22 and 24, the elongate member is a guidewire (Thome)

Regarding claims 11 and 12, Thome discloses the claimed invention except for the use of less than 1% nickel precipitation hardened stainless steel. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use

nickel free stainless steel, since it has been held to be within the general skill of worker in the art to select a known material on the basis of its suitability for the intended use a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

#### **(10) Response to Argument**

**Claim 1:** Applicant has argued that the phrase "concentrically arranged about" must mean that the second layer is outside of the super elastic layer. The examiner finds that the claim is broader than this interpretation. The term "arranged about" does not have to mean outside or exterior. One of ordinary skill in the art would not automatically assume that this phrase means outside or exterior. The two layers of Thome's device are clearly concentric, with the inner layer (second layer) abutting the super elastic layer. In support of this claim interpretation, the examiner notes that the applicant later uses the term "surrounded" (Claim 8) which is clearly to define that the layer is exterior or outside of the inner core.

**Claim 8:** See lines 3-6 of the claim which read, including all punctuation: "the composite elongate core including an inner core formed of a precipitation hardened material concentrically surround by a first layer formed of a superelastic material and having a proximal section and a distal section." The examiner has presented a reasonable interpretation of this claim language meaning "the composite elongate core including an inner core, formed of a precipitation hardened material, wherein the inner core is concentrically surrounded by a first layer of a superelastic material, and wherein the

inner core has a proximal section and a distal section." In other words, the applicant has interpreted the claims to specify that the super elastic layer has a proximal and distal section; the examiner has interpreted the claims to specify that the inner core has a proximal and distal section. The lack of punctuation makes the claim meaning unspecific and allows for the reasonable interpretation advanced by the examiner. The flexible body (176) clearly partially overlies the distal section of the inner core. Fig 25.

**Claims 26 and 27:** See the interpretation problems related the proximal and distal sections as discussed with regards to claim 8.

**Motivation to combine:** Applicant has argued (pg 9) that providing an alternate material is not a motivation to combine references. However, both Thome and Fagan are medical guide wires and both use similar materials (Hiperco and MP35N precipitation alloy, pg 17). The choice of a precipitation hardened alloy for the core of a medical guidewire is expressly disclosed in Fagan and one of ordinary skill in the art the time the invention was made would have recognized the two materials as equivalents and readily interchangeable.

#### **(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

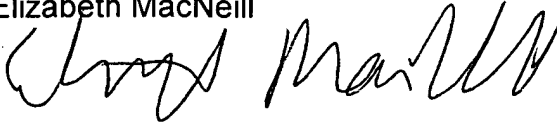
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For the above reasons, it is believed that the rejections should be sustained.

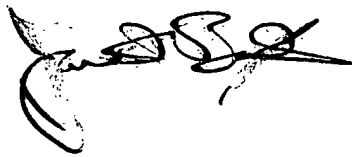
Respectfully submitted,

Elizabeth MacNeill



Conferees:

Janet Baxter



Kevin Sirmons

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

